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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/117,921	03/04/1999	PIERRE BROUN	PM255164	8452

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EXAMINER

MCELWAIN, ELIZABETH F

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 08/06/2002

94

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/117,921

Applicant(s)

BROUN ET AL.

Examiner

Elizabeth McElwain

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7-11 and 14-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7-11 and 14-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

The amendment filed June 5, 2002 has been entered.

Claims 2-6, 12-13 and 17-34 have been cancelled.

Claims 1, 7-9, 11 and 14-15 have been newly amended.

Claims 1, 7-11 and 14-16 are pending and are examined on the merits.

5 The text of those sections of Title 35, U.S. Code not included in this action can be found
in a prior Office action.

 Claims 7-9, 11, 14 and 15, and claim 16 dependent thereon, are rejected under 35
U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and
10 distinctly claim the subject matter which applicant regards as the invention.

 Claims 7-9, 11, 14 and 15, and claim 16, are indefinite in the recitation of "containing"
and "contains" with regard to a sequence, as it remains unclear if this terminology is considered
open or closed. Amendment of the claims to read "comprising" or "consisting of" would
overcome the rejection.

15 Claim 15 is also indefinite in that it fails to further limit the subject matter of claim 11.

 The following is a quotation of the first paragraph of 35 U.S.C. 112:

20 The specification shall contain a written description of the invention, and of the manner and
process of making and using it, in such full, clear, concise, and exact terms as to enable any
person skilled in the art to which it pertains, or with which it is most nearly connected, to
make and use the same and shall set forth the best mode contemplated by the inventor of
carrying out his invention.

 Claims 8, 11 and 15-16 are rejected under 35 U.S.C. 112, first paragraph, as containing
subject matter which was not described in the specification in such a way as to reasonably convey

to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a method of altering the amount of an unsaturated fatty acid in a seed of a plant by decreasing a fatty acid desaturase activity by transforming a plant with a sequence encoding a dominant negative mutant of a fatty acid
5 desaturase. However, the only dominant negative mutant of a fatty acid desaturase that has been described in the specification is a fatty acid desaturase in which one or more of the essential histidine residues have been mutated. The specification does not describe what other structural changes could be made to a fatty acid desaturase which would result in a dominant negative mutant.

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See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir.

1997), where it states:

15 “The name cDNA is not in itself a written description of that DNA;
it conveys no distinguishing information concerning its identity.
While the example provides a process for obtaining human insulin-
encoding cDNA, there is no further information in the patent
pertaining to that cDNA’s relevant structural or physical
characteristics; in other words, it thus does not describe human
insulin cDNA . . . Accordingly, the specification does not provide a
20 written description of the invention . . .”

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

Claims 8, 9, 11 and 14-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are drawn to a method of altering the amount of an unsaturated fatty acid in a seed of a plant by decreasing a fatty acid desaturase activity by transforming a plant with a sequence encoding a dominant negative mutant of a fatty acid desaturase. However, the specification does not provide any examples of a plant that has been transformed with a sequence encoding a dominant negative mutant of a fatty acid desaturase that results in decreasing a fatty acid desaturase activity. In addition, the specification lacks guidance with regard to identifying sequences that would encode a dominant negative mutant of a fatty acid desaturase.

De Luca teaches that modifying plant biosynthetic pathways by transforming plants with genes encoding enzymes involved in a pathway is highly unpredictable (see the paragraph bridging the columns on page 225N, for example), and that “on many occasions desired goals have been impossible to achieve” (see the last paragraph on page 228N).

Thus, given the unpredictability of identifying sequences that are dominant negative mutants for fatty acid desaturases and for decreasing a fatty acid desaturase activity of a plant by transforming the plant with said sequence; the lack of guidance in the specification for identifying and characterizing any other sequences that are dominant negative mutants for fatty acid desaturases; given the lack of working examples of any dominant negative mutants for fatty acid desaturases that will decrease fatty acid desaturase activity in a plant; and the breadth of the

claims, which encompass use of any dominant negative mutant genes of fatty acid desaturases to decrease fatty acid desaturase activity in any plant; and given the state of the art and the high level of skill in the transgenic plant art, it would require undue experimentation by one skilled in the art to make and use the invention as broadly claimed.

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Claims 1, 7, and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Lightner et al (U.S. Patent 6,372,965).

The claims are drawn to a method of altering the amount of an unsaturated fatty acid in a seed of a plant by decreasing a fatty acid desaturase activity by genetic manipulation of a fatty acid desaturase, including by transforming a plant, such as soybean with a nucleic acid sequence encoding a fatty acid desaturase.

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Lightner et al teach a method of altering the amount of an unsaturated fatty acid in a seed of a plant by decreasing a fatty acid desaturase activity by genetic manipulation of a fatty acid desaturase, including by introduction of a recombinant construct comprising a nucleic acid sequence encoding a fatty acid desaturase into *Glycine max*, which is soybean (see column 8, lines 34-50; columns 27-29; and columns 49-50, for example).

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Applicant's arguments filed June 5, 2002 have been fully considered but they are not relevant to the present rejections.

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No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (703) 308-1794. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM.

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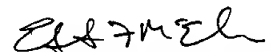
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone number for this Group is (703) 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

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Any inquiry of a general nature or relating to the status of this application should be directed to the legal analyst, Gwendolyn Payne, whose telephone number is (703) 305-2475, or to the Group receptionist whose telephone number is (703) 308-0196.

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Elizabeth F. McElwain, Ph.D.
August 1, 2002


ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600